

340B Drug Pricing Program Overview

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**Health Resources and Services Administration
U.S. Department of Health and Human Services**



Overview

- The 340B Drug Pricing Program (340B Program) requires drug manufacturers to provide covered outpatient drugs to eligible covered entities at significantly reduced prices
- Average savings of 25 – 50%
- Estimated \$6 billion in 340B drug purchases last year
- Manufacturers that participate in Medicaid must also participate in the 340B Program
- The 340B Program enables covered entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.
- Eligible covered entities are defined in the statute
- To participate in the 340B Program, eligible covered entities must register and be enrolled with the 340B Program, and comply with all 340B Program requirements



Legislative History

- 1992: creation of the 340B Program
- 1996: HRSA issued guidance for an individual to qualify as a patient of a 340B covered entity
- 2010: Congress passed ACA, which broadened the 340B Program to cover four additional types of hospital entities
 - Free-standing Cancer Hospitals, Rural Referral Centers, Sole Community Hospitals and Critical Access Hospitals



Eligible Covered Entities

Federal Grantees/Designees	Certain Hospitals
<ul style="list-style-type: none">• Federally qualified health center• Federally qualified health center look-alikes• Title X Family Planning grantees• State Aids drug assistance programs• Ryan White Care Act grantees (A,B,C,D,F)• Black lung clinics• Hemophilia treatment centers• Native Hawaiian health centers• Urban Indian organizations• Sexually transmitted disease grantees• Tuberculosis grantees	<ul style="list-style-type: none">• Disproportionate share hospitals• Children's hospitals• Critical access hospitals• Free standing cancer hospitals• Rural referral centers• Sole community hospitals



Registration

- Ensure eligibility of covered entity
- Provide accurate covered entity information
- Ensure transparency of 340B drug utilization
- Maintenance of 340B database record
 - Covered entity is responsible for keeping record up to date at all times



Registration Process

- Registration Deadlines

Registration Period	January 1 – January 15	April 1 – April 15	July 1 – July 15	October 1 – October 15
Start Date	April 1	July 1	October 1	January 1

- Includes new covered entities and contract pharmacies
- Captures Medicaid billing information
- Change requests:** changes to information on existing sites listed in the 340B database. Allow up to 2 weeks for a change request to be approved.



340B Database

- Entities are not eligible for the 340B Program unless listed in the 340B database
- Each clinic/site will receive a unique 340B ID
- Entities are required to keep their information updated in the database, and ensure site are properly listed
- Wholesalers will not ship 340B drugs unless there is an exact site/address match in the 340B database
- The 340B database is separate from the Office of Population Affairs' grantee database - both must be kept up-to-date



Eligibility: Title X Family Planning Clinics

In order to enroll in the 340B program, a Family Planning clinic must receive:

Title X Family Planning funding, as authorized by Section 1001 of the Public Health Service Act (42 USCS§300)

- Title X funding is awarded through the Office of Population Affairs



340B Registration Process

1. Determine eligibility – is the clinic receiving Title X funding? Find out what the Federal grant number is (hint: FPHPA#####)
2. Complete the online registration during an open registration period:
<http://opanet.hrsa.gov/opa/Default.aspx>
3. OPA verified eligibility of the clinic by contacting a State-level Title X program manager
4. Await final decision from OPA. OPA will email the AO and contact person if more information is needed

Participation Requirements

- The covered entity must immediately inform HRSA of a change in eligibility status and the entity must stop purchasing immediately
- Entities must report non-compliance to HRSA
- Pharmacies should not have their own 340B ID – they are not eligible covered entities:
 - In-house pharmacies can be listed as a shipping addresses
 - Contract pharmacies must be registered through the contract pharmacy registration process
- Off-site outpatient facilities and subgrantee sites are required to register and be listed in the database



340B Drug Delivery Options

- Covered entity owned/in-house pharmacy
- Contract pharmacy
 - single independent or chain pharmacy
- Covered entity:
 - Maintains responsibility for 340B drug
 - Is responsible for 340B Program compliance, including oversight of contract pharmacies



Annual Recertification

- Required by statute (PHSA/ACA) to be completed annually
- Ensure accuracy of covered entity and contract pharmacy information in the 340B database
- Opportunity to update 340B database record
- Covered entities must self-disclose programmatic violations
- Covered entity's responsibility to ensure the accuracy of the information in the 340B database



Recertification Process

- All covered entities with an active 340B ID are required to recertify
- Before recertification, the clinic should verify that the AO and contact information is up to date
 - If not, submit 340B Program change form:
<http://opanet.hrsa.gov/OPA/CRPublicSearch.aspx>
- Monitor 340B Program webpage and your email for updates on when recertification will occur for your organization
- Recertification is not registration
- 340B Change form is different from performing recertification
- Review recertification user guide for more information
 - <http://opanet.hrsa.gov/OPA/Manuals/OPA%20Database%20Guide%20for%20Public%20Users%20-%20Recertification.pdf>



Recertification Process

- Include 340B ID when communicating with APEXUS or the 340B Program staff
- OPA recommends that the authorizing official and primary contact are different individuals
- PO boxes are authorized for billing addresses only
- When decertifying a site, be prepared to answer the following questions:
 - What is the reason for termination?
 - What is the date the covered entity became ineligible?
 - What is the last date 340B drugs were or will be purchased under this 340B ID?



Tips for Successful Recertification

- User names and passwords are not good forever and cannot be used to make continual changes to a covered entity database record
- Do not wait until the last days of recertification to request technical assistance
- Work with your IT Security Program managers to ensure SPAM filters will not block email from 340b.recertification@hrsa.gov
- Be prepared for questions from HRSA if you change critical information in your 340B database record such as a change of ownership or the addition of new addresses



Terminations/Decertifications

- A covered entity should stop purchasing 340B drugs the day they are no longer eligible (i.e., loss of grant funding, the clinic closes) and immediately notify HRSA
 - This should be done immediately through an online change request
- A covered entity must complete the change request including the following questions (dates are required):
 - A. The reason for termination
 - B. Date the entity became ineligible
 - C. The last date 340B drugs were or will be purchased under the 340B ID
 - D. A brief description of the facts surrounding the reason for termination
- A covered entity should not wait for the recertification timeframe to terminate an entity



Areas of Focus

- Eligibility
- Duplicate Discounts
- Diversion



Things to Know About Audits

- Responsibility for 340B Program compliance
 - Plan for oversight
- Policies and procedures compliant with 340B Program requirements
- Final Report
 - Agreement
 - Disagreement
- Corrective Action Plan (CAP)



HRSA Audits by the Numbers

as of 6/26/15

	FY 2012	FY 2013	FY 2014	FY 2015
Number of covered entities audited	51	94	99	138
• Outpatient facilities/sub- grantees	410	718	1476	1706
• Contract pharmacies	860	1937	4028	3233
Number of finalized reports	51	92	93	45



HRSA Audit Steps

Pre-Audit

- Engagement letter
- Scheduling
- Data request



HRSA Audit Steps

Onsite Audit

- Opening Meeting
- Staff interviews
- Data sample review



340B Audit Findings

- Eligibility
 - Incorrect 340B database entry
 - Lack of auditable records
 - Lack of written contract pharmacy agreement in place before registering contract pharmacy in 340B database
- Diversion
 - Ineligible patient
 - Inpatient status
 - Ineligible sites
- Duplicate Discount
 - Inaccurate information in the 340B Medicaid Exclusion File
 - Billing Medicaid for 340B drugs at contract pharmacy when no arrangement with state Medicaid agency has been communicated with HRSA



HRSA Audit Steps

Post-Audit

- Preliminary findings
- Notice and Hearing
- CAP
- Final Report
- Public letter
- Attestation



Post Audit Findings

- Covered entities have opportunity for notice and hearing
- Once a covered entity agrees to Final Report or time for disagreement has passed → must submit their corrective action plan (CAP) in 60 days
- Final audits and CAPs are posted in summary format on our website as audits are finalized
 - <http://www.hrsa.gov/opa/programintegrity/index.html>
- Results are used for educational purposes
 - create tools and resources for all covered entities



340B Peer-to-Peer Program

- High performing 340B entities (peer mentors) selected by HRSA - provide practical examples of 340B integrity and quality that serve as a resource for other entities
- Webinars held twice monthly (2nd and last Wednesday of each month) - topics presented by peer mentors
- Available for free to all 340B stakeholders
- Webinar Registration information: OPA website (www.hrsa.gov/opa), Apexus website (www.340bpvp.com).

HRSA Prime Vendor Program

- Apexus is contracted by HRSA as the Prime Vendor
- There is no cost to participate
- 340B University – education opportunities for covered entities
- Technical Assistance
- Drug price negotiation services
- Multiple wholesale distributor agreements



Contact Information

Office of Pharmacy Affairs (OPA)

Phone: 301-594-4353

Web: www.hrsa.gov/opa

Prime Vendor Program (PVP)

Phone: 1-888-340-2787

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Web: www.340bpvp.com

340B University-educational opportunity